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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/688,481	10/17/2003	Oswaldo da Costa e Silva	16313-0239	3938

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EXAMINER

COLLINS, CYNTHIA E

ART UNIT	PAPER NUMBER
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1638

DATE MAILED: 12/29/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/688,481	Applicant(s) COSTA E SILVA ET AL.	
	Examiner Cynthia Collins	Art Unit 1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 October 2003.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 1,2,11 and 12 is/are allowed.
- 6) ☒ Claim(s) 3-10,13-16,19 and 20 is/are rejected.
- 7) ☒ Claim(s) 17-18 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 17 October 2003 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>1003,1003</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Information Disclosure Statement

An initialed and dated copy of Applicant's IDS form 1449, filed October 17, 2005 is attached to the instant Office action.

Drawings

The drawings are objected to because the details in the images in figures 2-10 cannot be discerned. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

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The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 3-10, 13-16 and 19-20 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a written description rejection.

The claims are drawn to a nucleic acid encoding a polypeptide including nucleic acids that hybridize under defined stringency conditions to SEQ ID NO: 6 and nucleic acids that encode a polypeptide having at least 90% sequence identity with SEQ ID NO:11. The claims are also drawn to transgenic plant cells, plants and seed transformed with said nucleic acids, a recombinant expression cassette comprising said nucleic acids, and methods of using said nucleic acids to produce a transgenic plant.

The specification describes SEQ ID NO:6 (also designated PpGBP-1) as a nucleic acid sequence obtained from *Physcomitrella patens* that encodes an amino acid sequence of SEQ ID NO:11 (pages 43-79; sequence listing). The specification also describes SEQ ID NO:11 as exhibiting 82-84% sequence identity and 92-94% sequence similarity to five different GTP-binding proteins obtained from tobacco, tomato and *Arabidopsis* (page 48 Table 2). The specification additionally describes transgenic *Arabidopsis* plants transformed with a construct comprising SEQ ID NO:6 operably linked to a promoter in a sense orientation, said transgenic plants having increased drought stress and freezing tolerance as compared to nontransgenic wild type plants (pages 60-61 Tables 9 and 10 and Figures 2 and 6). The specification does not

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describe other isolated nucleic acids that hybridize under stringent conditions to SEQ ID NO: 6, or other isolated nucleic acids that encode a polypeptide having at least 90% sequence identity with SEQ ID NO:11.

The Federal Circuit has recently clarified the application of the written description requirement to nucleic acid sequences. The court stated that "A description of a genus of cDNAs may be achieved by means of recitation of a representative number of cDNAs, defined by nucleotide sequence, falling within the scope of the genus or of a recitation of structural features common to members of the genus, which features constitute a substantial portion of the genus." See *University of California v. Eli Lilly and Co.*, 119 F.3d 1559, 1569; 43 USPQ2d 1398, 1406 (Fed. Cir. 1997).

In the instant case Applicant has not described a representative number of species falling within the scope of the claimed genus which encompasses numerous undisclosed and uncharacterized nucleic acids that hybridize under stringent conditions to SEQ ID NO: 6 and that encode a polypeptide having at least 90% sequence identity with SEQ ID NO:11, nor the structural features unique to the genus.

Claims 3-10, 13-16 and 19-20 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a nucleic acid of SEQ ID NO:6 or a nucleic acid encoding SEQ ID NO:11, and for a transgenic plant or plant cell transformed with a construct comprising a nucleic acid of SEQ ID NO:6 or a nucleic acid encoding SEQ ID NO:11 operably linked to a promoter in a sense orientation, said plant exhibiting increased tolerance to drought or freezing stress, and methods of making said plants and cells, does not reasonably provide

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enablement for other types of nucleic acids, or for transgenic plant or plant cell transformed with other types nucleic acids. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

The claims are drawn to a nucleic acid encoding a polypeptide including nucleic acids that hybridize under defined stringency conditions to SEQ ID NO: 6 and nucleic acids that encode a polypeptide having at least 90% sequence identity with SEQ ID NO:11. The claims are also drawn to transgenic plant cells, plants and seed transformed with said nucleic acids, a recombinant expression cassette comprising said nucleic acids, and methods of using said nucleic acids to produce a transgenic plant.

The specification discloses the isolation from *Physcomitrella patens* of a nucleic acid of SEQ ID NO:6 (also designated PpGBP-1) that encodes an amino acid sequence of SEQ ID NO:11 (pages 43-79; sequence listing). The specification also discloses that SEQ ID NO:11 exhibits 82-84% sequence identity and 92-94% sequence similarity to five different GTP-binding proteins obtained from tobacco, tomato and *Arabidopsis* (page 48 Table 2). The specification additionally discloses how to use a nucleic acid of SEQ ID NO:6 to make transgenic *Arabidopsis* plants by transforming *Arabidopsis* plants with a construct comprising SEQ ID NO:10 operably linked to a promoter in a sense orientation, said transgenic plants having increased drought and freezing stress tolerance as compared to nontransgenic wild type plants (pages 60-61 Tables 9 and 10 and Figures 2 and 6). The specification does not disclose how to make and use other isolated nucleic acids that hybridize under stringent conditions to SEQ ID NO: 6, or other

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isolated nucleic acids that encode a polypeptide having at least 90% sequence identity with SEQ ID NO:11.

The full scope of the claimed invention is not enabled because the function of nucleic acid sequences that hybridize under stringent conditions to SEQ ID NO: 6, or of isolated nucleic acids that encode a polypeptide having at least 90% sequence identity with SEQ ID NO:11, is unpredictable, since structurally homologous sequences are not always functionally homologous.

See for example Doerks T. et al. (Protein annotation: detective work for function prediction. Trends Genet. 1998 Jun;14(6):248-50), who teach that incorrect or incomplete sequence information within a database affects the predictive capacity of the database (Page 248 column 1 paragraph 1). Doerks et al. also teach that query searches may identify shared homology with multiple groups of functionally unrelated proteins (Page 248 column 3 second full paragraph), that regions of shared homology may be nonfunctional regions (Page 248 column 3 third full paragraph), and that the degree of shared homology within a functional region does not always predict a conservation of the functional mechanism of that region (Page 248 column 3 fourth full paragraph).

See also, for example, Broun P et al. (Catalytic plasticity of fatty acid modification enzymes underlying chemical diversity of plant lipids. Science. 1998 Nov 13;282(5392):1315-7), who teach that a *Lesquerella fendleri* oleate hydroxylase having 81% sequence identity to an *Arabidopsis thaliana* oleate desaturase has only 71 % sequence identity to *Ricinus communis* oleate hydroxylase (1998, Science, Vol. 282, pages 1315-1317, page 1315 column 2 first full paragraph). Broun et al. also teach that as few as four amino acid substitutions can change an oleate 12-desaturase to a hydroxylase (paragraph spanning pages 1316-1317).

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In the instant case the specification does not provide sufficient guidance with respect to how to make nucleic acid sequences that hybridize under stringent conditions to SEQ ID NO: 6, or isolated nucleic acids that encode a polypeptide having at least 90% sequence identity with SEQ ID NO:11, that can be used to increase the tolerance of a plant transformed therewith to a specific type of stress. Absent such guidance one skilled in the art would have to test each of the myriad sequences encompassed by the claims for its effect on the tolerance of a plant transformed therewith to drought and freezing stress in order to discriminate between those sequences that increase plant stress tolerance and those that do not. Such a trial and error approach to practicing the claimed invention would constitute undue experimentation.

Allowable Subject Matter

Claims 1-2 and 11-12 are allowed.

Claims 17-18 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form.

Remarks

Claims 1-20 are deemed free of the prior art due to the failure of the prior art to teach or suggest a nucleic acid of SEQ ID NO:6 or encoding SEQ ID NO:11 or a nucleic acid that hybridizes under the defined stringency conditions to SEQ ID NO: 6 or a nucleic acid that encodes a polypeptide having at least 90% sequence identity with SEQ ID NO:11.

Claims 3-10, 13-16 and 19-20 are rejected

Claims 1-2 and 11-12 are allowed.

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Claims 17-18 are objected to.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Cynthia Collins whose telephone number is (571) 272-0794. The examiner can normally be reached on Monday-Friday 8:45 AM -5:15 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anne Marie Grunberg can be reached on (571) 272-0975. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Cynthia Collins
Primary Examiner
Art Unit 1638

CC


12/23/05